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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-945/S-005

Microbiology Review(s)

Product Quality Microbiology Review
Review for HFD-150

18 SEP 2002

NDA: 20-954/SCP-005

Drug Product Name
Proprietary: BUSULFEX® Injection
Non-proprietary: Busulfan
Drug Product Classification: 3P, Cytotoxic/Alkylating agent

Review Number: 1

Subject of this Review
Submission Date: 10 MAY 2002
Receipt Date: 13 MAY 2002
Consult Date: 21 MAY 2002
Date Assigned for Review: 05 JUN 2002

Submission History (for amendments only)
Date(s) of Previous Submission(s): (none)
Date(s) of Previous Micro Review(s): (none)

Applicant/Sponsor
Name: Orphan Medical, Inc.
Address: 13911 Ridgedale Drive, Suite 250, Minnetonka, MN 55305
Representative: Carol S. Curme
Telephone: (952) 513-6900

Name of Reviewer: David Hussong

Conclusion: APPROVE

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** CBE-30

2. **SUPPLEMENT PROVIDES FOR:** A new, alternate syringe 5-µm filter packaged with the sterile product.

3. **MANUFACTURING SITE:** [redacted]

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 60 mg ampule

5. **METHOD(S) OF STERILIZATION:** [redacted]

6. **PHARMACOLOGICAL CATEGORY:** Cytotoxic

B. **SUPPORTING/RELATED DOCUMENTS:** N/A

C. **REMARKS:** The filter change involves a component that is packaged with the ampule and, when used, is in contact with the sterile solution. The 5-µm rated filter does not add to sterility assurance because it is not intended to remove microorganisms.

The supplement was an submitted in electronic format.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability - APPROVE

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The alternate filter is added to the packaging and is used by the pharmacist preparing the patient dose. The filter is an approved medical device (reference to 510(k) application # K960928).

B. Brief Description of Microbiology Deficiencies - N/A

C. Assessment of Risk Due to Microbiology Deficiencies - N/A

III. Administrative

A. Reviewer's Signature /S/

B. Endorsement Block
Microbiologist/David Hussong
Microbiology Supervisor/Peter Cooney

C. CC Block
cc:
Original NDA 20-954
HFD- 150/Division File/NDA 20-954

Redacted 2

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/s/

David Hussong
11/14/02 10:06:17 AM
MICROBIOLOGIST

Peter Cooney
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MICROBIOLOGIST